CLAIMS

1-71. (Canceled)

72. (previously presented) A sustained release dosage form comprising azithromycin which meets the following in vitro criteria:

(1) $Q_{0.25} \leq$ 200 mg,

(2) $Q_1 \leq$ 500 mg,

(3) $Q_2 \leq$ 1000 mg,

(4) $Q_4 \leq$ 1500 mg, and

(5) $Q_6 \leq$ 2000 mg,

when said dosage form is tested in a USP rotating paddle apparatus, said apparatus being described in USP XXIII dissolution test chapter 711, and wherein the apparatus has paddles rotating at 50 rpm and contains 900 mL of pH 6.0 sodium dihydrogen phosphate buffer at 37°C;

wherein, if said dosage form is a capsule, said buffer is implemented to contain 0.1 mg/mL of trypsin

and wherein said dosage form releases not more than 70% of its contained azithromycin within one half hour.

73. (previously presented) A dosage form as defined in claim 72, wherein said azithromycin is embedded in a matrix, which releases said azithromycin by diffusion.

74. (previously presented) A dosage form as defined in claim 73, wherein said matrix remains substantially intact during the period of drug release.

75. (previously presented) A dosage form as defined in claim 73, wherein said azithromycin is embedded in a matrix which releases said azithromycin by eroding.

76. (previously presented) A dosage form as defined in claim 75, wherein said matrix comprises hydroxypropyl methylcellulose.

77. (withdrawn) A dosage form as defined in claim 75, wherein said matrix comprises hydroxypropyl cellulose.

78. (withdrawn) A dosage form as defined in claim 75, wherein said matrix comprises poly(ethylene oxide).

79. (withdrawn) A dosage form as defined in claim 75, wherein said matrix comprises polyacrylic acid.

80. (previously presented) A dosage form as defined in claim 72, comprising a reservoir of azithromycin encased in a membrane which limits the release rate of azithromycin to said GI tract by diffusion.

81. (previously presented) A dosage form as defined in claim 80, in the form of a tablet coated with a membrane.

82. (previously presented) A dosage form as defined in claim 72, in the form of a multiparticulate comprising particles each of which is coated with a membrane which limits the release rate of said azithromycin by diffusion.

83. (previously presented) A dosage form as defined in claim 73, wherein a portion of the outside surface of said matrix is covered with an impermeable coating and the remainder of said outside surface is uncovered.

84. (previously presented) A dosage form as defined in claim 83, substantially in the shape of a cylinder wherein said impermeable coating covers one or both of the opposing flat surfaces thereof.

85. (previously presented) A dosage form as defined in claim 83, substantially in the shape of a cylinder wherein said impermeable coating covers only the radial surface thereof.

86. (previously presented) A dosage form as defined in claim 83, in the form of a tablet, wherein said uncovered area is in the form of an opening through said impermeable coating.

87. (withdrawn) A dosage form as defined in claim 83, in the form of a tablet, wherein said uncovered area is in the form of a passageway which penetrates through the entire device.

88. (withdrawn) A dosage form as defined in claim 83, in the form of a tablet, wherein said uncovered area is in the form of one or more slits through said impermeable coating or in the form of one or more strips removed therefrom.

89. (withdrawn) A dosage form as defined in claim 83, substantially in the form of a cone, wherein the uncovered area an opening for drug transport at or near the apex of the cone.

90. (withdrawn) A dosage form as defined in claim 83, substantially in the shape of a hemisphere, wherein the uncovered area is in the form of an opening for drug transport at or near the center of the flat face of the hemisphere.

91. (withdrawn) A dosage form as defined in claim 83, substantially in the shape of a half-cylinder, wherein the uncovered area is in the form of one or more slits at or near the centerline of the flat face of said half-cylinder.

92. (withdrawn) A dosage form as defined in claim 72 in the form of a coated bi-layer tablet, wherein one layer of said tablet comprises a water-swellable composition and the second layer of said tablet comprises a dispensible azithromycin composition, said tablet being coated with a water-permeable membrane which is substantially impermeable to azithromycin, and which contains one or more perforations or passageways for exposing the azithromycin-containing composition to the use environment.

93. (previously presented) A dosage form as defined in claim 72 in the form of a coated tablet comprising a water-soluble salt of azithromycin, said tablet having a water-permeable coating which is substantially impermeable to azithromycin and substantially non-porous, said coating containing one or more perforations or passageways, for exposing the interior of the tablet to a use environment.

94. (previously presented) A dosage form as defined in claim 72 in the form of a coated tablet comprising azithromycin, said tablet having a porous coating which permits transport of both water and azithromycin through said porous coating.

95. (previously presented) A dosage form as defined in claim 72 in the form of a coated multiparticulate formulation wherein each particle comprises azithromycin and has a porous coating which permits transport of both water and azithromycin through said porous coating.

96-124 (canceled)

125. (previously presented) A sustained release dosage form comprising azithromycin for ingestion by a mammal which meets, based on the weight of said mammal, the following in vitro criteria:

(1) $Q_{0.25} \leq$ 4 mg/Kg of mammal weight,

(2) $Q_1 \leq$ 10 mg/Kg of mammal weight,

(3) $Q_2 \leq$ 20 mg/Kg of mammal weight,

(4) $Q_4 \leq$ 30 mg/Kg of mammal weight, and

(5) $Q_6 \leq$ 40 mg/Kg of mammal weight,

when said dosage form is tested in a USP rotating paddle apparatus, said apparatus being described in USP XXIII dissolution test chapter 711, and wherein the apparatus has paddles rotating at 50 rpm and contains 900 mL of pH 6.0 sodium dihydrogen phosphate buffer at 37°C;

wherein, if said dosage form is a capsule, said buffer is implemented to contain 0.1 mg/mL of trypsin

and wherein said dosage form releases not more than 70% of its contained azithromycin within one half hour ~~following ingestion~~.

126. (previously presented) A dosage form as defined in claim 125, wherein said azithromycin is embedded in a matrix, which releases said azithromycin by diffusion.

127. (previously presented) A dosage form as defined in claim 126, wherein said matrix remains substantially intact during the period of drug release.

128. (previously presented) A dosage form as defined in claim 126, wherein said azithromycin is embedded in a matrix which releases said azithromycin by eroding.

129. (previously presented) A dosage form as defined in claim 128, wherein said matrix comprises hydroxypropyl methylcellulose.

130. (withdrawn) A dosage form as defined in claim 128, wherein said matrix comprises hydroxypropyl cellulose.

131. (withdrawn) A dosage form as defined in claim 128, wherein said matrix comprises poly(ethylene oxide).

132. (withdrawn) A dosage form as defined in claim 128, wherein said matrix comprises polyacrylic acid.

133. (previously presented) A dosage form as defined in claim 125, comprising a reservoir of azithromycin encased in a membrane which limits the release rate of azithromycin to said GI tract by diffusion.

134. (previously presented) A dosage form as defined in claim 133, in the form of a tablet coated with a membrane.

135. (currently amended) A dosage form as defined in claim 133 ~~claim 135~~, in the form of a multiparticulate comprising particles each of which is coated with a membrane which limits the release rate of said azithromycin by diffusion.

136. (previously presented) A dosage form as defined in claim 126, wherein a portion of the outside surface of said matrix is covered with an impermeable coating and the remainder of said outside surface is uncovered.

137. (previously presented) A dosage form as defined in claim 136, substantially in the shape of a cylinder wherein said impermeable coating covers one or both of the opposing flat surfaces thereof.

138. (previously presented) A dosage form as defined in claim 136, substantially in the shape of a cylinder wherein said impermeable coating covers only the radial surface thereof.

139. (previously presented) A dosage form as defined in claim 136, in the form of a tablet, wherein said uncovered area is in the form of an opening through said impermeable coating.

140. (withdrawn) A dosage form as defined in claim 136, in the form of a tablet, wherein said uncovered area is in the form of a passageway which penetrates through the entire device.

141. (withdrawn) A dosage form as defined in claim 136, in the form of a tablet, wherein said uncovered area is in the form of one or more slits through said impermeable coating or in the form of one or more strips removed therefrom.

142. (withdrawn) A dosage form as defined in claim 136, substantially in the form of a cone, wherein the uncovered area is an opening for drug transport at or near the apex of the cone.

143. (withdrawn) A dosage form as defined in claim 136, substantially in the shape of a hemisphere, wherein the uncovered area is in the form of an opening for drug transport at or near the center of the flat face of the hemisphere.

144. (withdrawn) A dosage form as defined in claim 136, substantially in the shape of a half-cylinder, wherein the uncovered area is in the form of one or more slits at or near the centerline of the flat face of said half-cylinder.

145. (withdrawn) A dosage form as defined in claim 125 in the form of a coated bi-layer tablet, wherein one layer of said tablet comprises a water-swellable composition and the second layer of said tablet comprises a dispensible azithromycin composition, said tablet being coated with a water-permeable membrane which is substantially impermeable to azithromycin, and which contains one or more perforations or

passageways for exposing the azithromycin-containing composition to the use environment.

146. (previously presented) A dosage form as defined in claim 125 in the form of a coated tablet comprising a water-soluble salt of azithromycin, said tablet having a water-permeable coating which is substantially impermeable to azithromycin and substantially non-porous, said coating containing one or more perforations or passageways, for exposing the interior of the tablet to a use environment.

147. (previously presented) A dosage form as defined in claim 125 in the form of a coated tablet comprising azithromycin, said tablet having a porous coating which permits transport of both water and azithromycin through said porous coating.

148. (previously presented) A dosage form as defined in claim 125 in the form of a coated multiparticulate formulation wherein each particle comprises azithromycin and has a porous coating which permits transport of both water and azithromycin through said porous coating.